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APPLICATION NO.	FILING DATE	FIRST NAME INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 872,338	06/01/2001	Timothy Gardner	CEI-004	2890

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Testa, Hurwitz & Thibault, LLP
Patent Administrator
High Street Tower
125 High Street
Boston, MA 02110

EXAMINER

LEFFERS JR, GERALD G

ARTICLE	PAPER NUMBER
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2636

DATE MAILED 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872.338

Applicant(s)

GARDNER ET AL

Examiner

Gerald G Leffers Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a recombinant multi-state genetic oscillator comprising at least 3 nucleic acids having at least 4 open reading frames (ORFs) linked to at least 3 promoters, classified in class 536, subclass 23.1.
- II. Claims 13-19, drawn to a method of periodically expressing a gene of interest (GOI) in a host cell, classified in class 435, subclass 69.1.
- III. Claims 20-31, drawn to recombinant multi-state genetic oscillator, classified in class 536, subclass 23.1.
- IV. Claims 32-38, drawn to methods of periodically expressing a gene of interest, classified in class 435, subclass 69.1.
- V. Claims 39-50, drawn to recombinant multi-state genetic oscillator, classified in class 536, subclass 23.1.
- VI. Claims 51-57, drawn to methods of periodically expressing a gene of interest, classified in class 435, subclass 69.1.
- VII. Claims 58-66, drawn to recombinant multi-state genetic oscillator, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, III, V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions are not disclosed as usable together and have different modes of operation, functions and effects. For each of the different recombinant multi-state genetic oscillators there is a different combination and arrangement of regulatory sequences operatively linked to different regulatory proteins that gives each of the different oscillators different characteristics with regard to regulating the expression of a GOI. Therefore, the structural, functional characteristics of each of the different oscillators is different from the others and does not make the others obvious.

Inventions of Groups II, IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation, functions and effects. Each of the different methods features the use of a different recombinant multi-state genetic oscillator comprising a different combination and arrangement of regulatory sequences operatively linked to different regulatory proteins, resulting in distinct characteristics with regard to regulating the expression of a GOI. Therefore, the modes of operation, function and effects of each of the different methods is different from the others and does not make the others obvious.

Inventions of Groups I, III, V and VII and Groups II, IV and VI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids

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of the recombinant multi-state genetic oscillator of Groups I, III, V and VII can be labeled and used to identify similar regulatory genes or promoters from different cell types. Alternatively, the multi-state genetic oscillators of Groups I, III, V and VII can be used to express a gene of interest from an even more complicated expression system comprising additional nucleic acid constructs.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. In addition, for those groups with a similar patent classification, the non-patent literature search for each of the different groups is different based upon the different arrangement and composition of the nucleic acid elements of the genetic oscillators upon which each group is based. The degree of difference is such that there is a burdensome search requirement for examining the different groups together.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

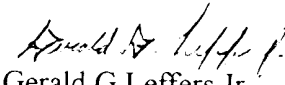
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
December 12, 2002